

Serial No.: 10/502290  
Group Art Unit No.: 1651

**Amendments to the Claims:**

1.. (Original): A DNA pharmaceutical agent dosage form, having a dense core element coated with a solid reservoir medium containing the DNA pharmaceutical agent.

2. (Original): A DNA pharmaceutical agent dosage form as claimed in claim 1, further comprising a stabilising agent that inhibits the degradative effects of free radicals.

3. (Original): A DNA pharmaceutical agent dosage form as claimed in claim 2 wherein the stabilising agent is one or both of a metal ion chelator and a free radical scavenger.

4. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the metal ion chelator is selected from the group consisting of: inositol hexaphosphate; tripolyphosphate; succinic and malic acid; ethylenediamine tetraacetic acid (EDTA); tris (hydroxymethyl) amino methane (TRIS); Desferal; diethylenetriaminepentaacetic acid (DTPA); and ethylenediamindihydroxyphenylacetic acid (EDDHA).

5. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the free radical scavenger is selected from the group consisting of ethanol, methionine and glutathione.

6. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 2 wherein the stabilising agent that inhibits the degradative effects of free radicals, is a member selected from the group consisting of: Phosphate buffered ethanol solution in combination with methionine or EDTA; and Tris buffered EDTA in combination with methionine or ethanol or a combination of methionine and ethanol.

7. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the solid reservoir medium is an amorphous polyol.

8. (Original): A DNA pharmaceutical agent dosage form as claimed in claim 7, wherein the polyol is a stabilizing polyol.

Serial No.: 10/502290  
Group Art Unit No.: 1651

9. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the solid biodegradable reservoir medium is a sugar.

10. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 9 wherein the sugar is a member selected from the group consisting of lactose, glucose, sucrose, raffinose and trehalose.

11. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the solid reservoir medium is in the form of a glass.

12. (Original): A DNA pharmaceutical agent dosage form as claimed in claim 11, wherein the solid reservoir medium is in the form of a sugar glass.

13. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the DNA pharmaceutical agent is supercoiled plasmid DNA.

14. (Original): A DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the supercoiled plasmid DNA is stabilized such that after storage at 37°C for 4 weeks greater than 50% of the DNA remains in its supercoiled form.

15. (Original): A DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the DNA is stabilized such that when released the ratio of monomer:dimer supercoiled form is within the range of 0.8:1.2.

16. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the DNA pharmaceutical agent is a vaccine.

17. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the solid reservoir medium further comprises a member selected from the group consisting of vaccine adjuvant, transfection facilitating agent, DNAase inhibitor and a crystal poisoner.

Serial No.: 10/502290  
Group Art Unit No.: 1651

18. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 17, wherein the vaccine adjuvant is a member selected from the group consisting of CpG, a synthetic imidazoquinoline, tucerasol, a cytokine, MPL, QS21, QS7 and an oil in water emulsion.

19. (Previously Presented): A DNA pharmaceutical agent dosage form, as claimed in claim 1 wherein the dense core element comprises microbeads of a mean particle diameter of between 0.5 to 10  $\mu\text{m}$ .

20. (Previously Presented): A DNA pharmaceutical agent dosage form as claimed in claim 19, wherein the microbeads are gold or tungsten microbeads.

21. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 1, comprising making a solution of DNA pharmaceutical agent, reservoir medium, and stabilising agent that inhibits the degradative effects of free radicals in an solvent, followed by coating the at least one dense core element with said solution, and removing the solvent to form a solid reservoir medium containing the pharmaceutical agent and agent that inhibits the degradative effects of free radicals.

22. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 21, wherein the reservoir medium is a sugar.

23. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 22 wherein the concentration of sugar prior to removing the solvent is in the range of 20-40% w/v.

24. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 23, wherein the solvent is demetalated prior to the process.